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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,164	04/01/2004	Esther Regina de Rooij	2183-6412US	1592

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

NOTIFICATION DATE	DELIVERY MODE
10/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/817,164	DE ROOIJ ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,6,7 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,6,7 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 27, 2007 has been entered. Claims 2-4, 6, 7 and 17 are pending and under examination.

2. The rejection of claims 2-4, 6, 7, 14, 16 and 17 under 35 U.S.C. 102(b) as being anticipated by Cassol *et al.* (*Mem. Inst. Oswaldo Cruz*, Rio de Janeiro, 1996, 91(3):351-358), is moot with regard to cancelled claims 14 and 16, and withdrawn with regard to claims 2-4, 6, 7 and 17, in view of Applicant's amendment.

3. The rejection of claims 2, 6, 14, 16 and 17 remain rejected under 35 U.S.C. 103(a) as being obvious over Moye *et al.* (*4th Conference on Retroviruses and Opportunistic Infections*, 1997, Abstract, cited in IDS filed 8/9/06, "Moye"), is moot in view of the cancellation of claims 14 and 16, and Applicant's amendment to claims 2, 6 and 17.

Claims Summary

4. The claims are drawn to a process for preparing at least one sample for a method of detecting and quantifying the total HIV nucleic acid present in the sample, said process comprising:

a) administering at least 100 microliters of the sample to a piece of filter paper capable of absorbing the sample, wherein the absorption results in a at least one spot,

b) drying the filter paper,

c) excising the spot from the surrounding filter paper,

d) extracting nucleic acid from the at least one spot of the at least one sample with a chaotropic nucleic acid isolation solution,

e) detecting HIV nucleic acid of interest, if present, and

f) quantifying the total HIV nucleic acid of interest in the sample.

In some embodiments, at least 200 or at least 250 microliters of sample is administered to the filter paper. In other embodiments, at least two samples are administered to the filter paper. Specifically, a known amount of a reference nucleic acid is administered to the filter paper. The HIV nucleic acid is from HIV-1.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-4, 6, 7 and 17 are rejected under 35 U.S.C. 103(a) as being obvious over Cassol *et al.* (Journal of Clinical Microbiology, 1997, 35(11):2795-2801, "Cassol 1997") in view of Cassol *et al.* (*Mem. Inst. Oswaldo Cruz*, Rio de Janeiro, 1996, 91(3):351-358, "Cassol 1996") and Gillespie (US Patent 5,482,834). The claims are summarized above.

The Cassol 1997 disclosure is directed to the quantification of HIV-1 RNA from dried plasma spots (abstract). The plasma spots were aliquoted on filter paper and stored for as long as two weeks prior to analysis by PCR (abstract). The Cassol 1997 reference does not teach the use of at least 100 microliters of sample for a single spot, nor does the Cassol 1997 reference disclose the use of a chaotropic nucleic acid isolation solution for extracting nucleic acid from the sample.

However, the Cassol 1996 reference discloses a method for the direct automated sequencing of HIV-1 field isolates from dried blood collected on filter paper, described on pages 355-356. The method includes the collection of blood by venipuncture and application of approximately 2 milliliters (2000 microliters) to filter paper via drops. The filter paper is air dried for three hours and placed in individual envelopes for storage/shipment for as long as two weeks (abstract). The samples are excised from the filter paper and further processed (page 351, second column, last partial sentence). It would have been obvious to detect total HIV-1 RNA, as taught by Cassol 1997, using the similar methods of the Cassol 1996 reference. The main difference is the amount of sample aliquoted onto the filter paper. Since the 2000 microliter spot was adequate for quantifying particular HIV nucleic acid of interest, it is expected to also be adequate for total HIV-1 nucleic acid quantification. Given the quantification of total HIV-1 RNA in the Cassol 1997 reference using 50 microliters, and the success of using 2000 microliters to also detect HIV-1 RNA (specific portions), one would reasonably expect that total RNA would be able to be quantified using either the 50 microliters or the 2000 microliters of sample. Given the finite number of choices (50 or 2000 microliters) that are both known to have

predictable results (quantification of HIV-1 RNA, total of RNA of interest), the invention as a whole would have been obvious.

Further, although the Cassol 1997 reference does not disclose the use of chaotropic nucleic acid isolation solution for extracting nucleic acid from the sample, Gillespie discloses the use of a chaotropic salt solution along with nucleic acid probes to improve hybridization of probes with their targets (abstract). Gillespie teaches that a chaotropic salt dissolves a biological source of RNA, such as cells and bacteria (col. 6, line 65 through col. 7, lines 1-13). The salts are also used to expose DNA from its sources (col. 8, lines 19-47). It would have been obvious to use the chaotropic salts suggested by Gillespie in the methods of Cassol. One would have been motivated to use the chaotropic salts to improve the hybridization in PCR probes to nucleic acid. One would have had a reasonable expectation of success that the use of a chaotropic salt solution along with nucleic acid probes would improve hybridization of probes with their targets (Gillespie, abstract) in view of Gillespie's salts being useful in methods of detecting HIV nucleic acid in blood (Examples 16 and 17).

With regard to the limitation in claim 6 about the administration of at least two samples to the filter paper, this would have been an obvious embodiment given a desire to have more than one sample available to compare and re-test, if necessary. With regard to the limitation in claim 7 about the administration of a known amount of a reference nucleic acid to the filter paper, this is also an obvious embodiment in view of the need to have a control with which to compare the test samples. These steps do not render the main inventive concept patentably distinct from the prior art. Therefore, the invention as a whole would have been *prima facie* obvious to one or ordinary skill in the art at the time of the invention.

Conclusion

6. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30), alternate Fridays off,. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/ 10-16-2007
Primary Examiner, TC1600